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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,089	10/10/2001	Marie B. Connell-Porceddu	2411-111	4802
6449	7590	04/09/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			BAUM, STUART F	
		ART UNIT		PAPER NUMBER
		1638		

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/973,089	CONNELL-PORCEDDU ET AL.
	Examiner	Art Unit
	Stuart F. Baum	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 January 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5-8,10,11,14-17,19,20 and 22-43 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3,5-8,10,11,14-17,19,20 and 22-43 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on January 14, 2004 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/973,089 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1-3, 5-8, 10-11, 14-17, 19-20, and 22-43 are pending.

Claims 4, 9, 12-13, 18, and 21 have been canceled.

2. Claims 1-3, 5-8, 10-11, 14-17, 19-20, and 22-43 are examined in the present office action.

Specification

3. The use of the trademarks GELRITE, BIOLISTIC, PECAP, GENETICIN, MAGENTA, and TIMENTIN has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

Art Unit: 1638

in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-8, 10-11, 14-17, 19-20, 22-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wenck et al (1999, Plant Molecular Biology 39(3):407-416) taken with Rutter et al (1998, U.S. Patent 5,731,204) and Levee et al (1999, Molecular Breeding 5:429-440).

The claims are drawn to a method for regenerating genetically modified Southern yellow pine plants and hybrids thereof, comprising selecting transgenic embryogenic pine cells using a selection medium comprising a selection agent and an agent that regulates differentiation selected from the group consisting of abscisic acid (ABA), polyethylene glycol (PEG) and a gelling agent in an amount between about 3% and about 5% or between about 0.5% and about 1.5%, wherein the gelling agent is gellan gum, and regenerating genetically modified plants from said transgenic embryogenic pine cells. The method includes transformation by *Agrobacterium*. Applicants' claims are also drawn to culturing said cells on a support membrane which is subsequently placed over a layer, wherein the layer either liquid or a gelled medium or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from a material selected from the group consisting of polyester, polypropylene and a liquid permeable fluoropolymer fabric. Lastly, the claims are drawn to eradicating *Agrobacterium* from the pine cells following transformation.

Wenck et al teach a method of genetically transforming Norway spruce using *Agrobacterium* and selecting the transformed embryogenic lines using kanamycin as an agent to select transformants and incorporating into the media abscisic acid which acts as an agent to regulate differentiation of embryos from embryogenic cells (page 409, left column, first line and right column, 'Embryo maturation' paragraph, respectively).

Wenck et al do not teach transforming and regenerating genetically modified Southern yellow pine plants, e.g., *Pinus taeda*, using PEG and gellan gum at a concentration of about 3% to 5%, or about 0.5% to about 1.5%. Wenck et al also do not teach placing cells on a support membrane which is subsequently placed over a layer, wherein the layer either liquid or a gelled medium or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from a material selected from the group consisting of polyester, polypropylene and a liquid permeable fluoropolymer fabric. Wenck et al also do not teach eradicating *Agrobacterium* from the pine cells following transformation.

Rutter et al teach a method of regenerating a Southern yellow pine plant, i.e. *Pinus taeda* using ABA, PEG and gellan gum at a concentration between 3% to 5%, and 0.5% to about 1.5% in their media to enhance regeneration efficiency (see columns 23 and 24, claims 9 and 10, for example).

Levee et al teach a method of regenerating transformed pine cells comprising culturing the cells on a support membrane and placing the support membrane over a layer of medium comprising a selection agent. Levee et al also teach eradicating *Agrobacterium* after transformation using tetracycline (page 431, Transformation procedure).

Given the recognition of those of ordinary skill in the art of the value of producing a transformed pine plant comprising cocultivating *Agrobacterium* with embryogenic pine suspension-cultured cells and then selecting said cells on media containing a selection agent and ABA which acts as an agent that regulates differentiation, to produce transformed plants as taught by Wenck et al, it would have been obvious to modify this method by incorporating PEG or gellan gum to enhance the efficiency of regeneration of genetically modified embryogenic

pine cultures as taught by Rutter et al. to produce large numbers of individual clones for reforestation purposes (column 1, lines 28-29) and to further modify this procedure by culturing the embryogenic suspension-cultured cells on a support membrane comprising filtering the liquid medium and cells through a filter (i.e., support membrane) supported by a Buchner funnel, and then placing the support membrane on medium containing a selection agent and chemical to eradicate *Agrobacterium* as taught by Levee et al. The motivation to use this method is that large numbers of transformed cells can be processed with a minimal amount of damage to the cells. Placing the support membrane on solid or liquid medium is a design choice. In both instances, the support membrane would become saturated with the medium on which it was placed, thereby placing the cells in contact with either, a selection agent, an agent that regulates differentiation, or an agent that eradicates *Agrobacterium*. The choice of material for the support membrane would be the optimization of process parameters that would not confer patentable distinction on the claimed invention. Given the lack of evidence to the contrary, regenerating one pine species or another, is a design chose that would not confer patentable distinction on the claimed invention.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant remarks/Office response for 103 Rejection

Applicant's arguments filed 1/14/2004 have been fully considered but they are not persuasive.

Applicants' arguments are summarized together for the relevant references. Applicants contend that Wenck et al teach the regeneration of genetically modified plants of Norway spruce and do not teach the regeneration of genetically modified plants of Southern yellow pines, such as *Pinus taeda* (page 9, 3rd full paragraph). Applicants contend that Wenck et al specifically state that stable transformants of loblolly pine (i.e., *Pinus taeda*) were not recovered as well as no plants were regenerated from said cells (page 9, bottom of 3rd full paragraph). Applicants contend that Rutter et al do not teach transformation of pine of the genus *Pinus* or a disclosure of transformation efficiency (page 10, 2nd paragraph). Since there is no disclosure of transformation, there is no disclosure of selection of transgenic embryogenic cells. Thus, Rutter et al do not disclose using ABA, PEG or a gelling agent in the specified amount in a selection medium which is used for selecting embryogenic pine cells of the genus *Pinus*. Applicants also contend, that since Rutter el al does not teach transformation, there is no reason to combine with Wenck et al (page 10, bottom of 2nd paragraph). Applicants also contend that Levee et al do not disclose the use of ABA, PEG or a gelling agent in the specified amount in a selection medium for selecting transgenic embryogenic pine cells of the genus *Pinus* selected from the group consisting of Southern yellow pines and hybrids thereof (page 10, 4th paragraph). Applicants contend that Levee et al disclose *Agrobacterium* transformation of white pine, *Pinus strobes*, which is a soft pine and not a hard pine, as is Southern yellow pines. Applicants contend that it is known in the art that embryogenesis systems of soft pine are different from those for hard

pines (page 12, top paragraph). Applicants contend that the Examiner has only showed regeneration of soft pines and not of hard pines. Furthermore, Applicants submit that there have not been any reports of the regeneration of *Agrobacterium* transformed pine plants of the genus *Pinus* (page 12, top paragraph). Applicants assert that a 1.132 Declaration is being prepared which asserts known differences between hard and soft pines and which provides further evidence of the non-obviousness of the present invention (page 12, end of top paragraph).

The Office contends, that absent evidence to the contrary, the method of Wenck et al of transforming and regenerating one conifer, Norway spruce, can be applied to transforming and regenerating another conifer, that being Southern yellow pines. The Office contends that a component of the transformation of plants, is the ability to regenerate plants from genetically modified plant cells. The regeneration process is separate from the transformation process and the two separate processes can be combined to achieve regeneration of genetically modified plant cells, as is specified in Applicants' claims. Rutter et al disclose a protocol for the regeneration of plants from plant cells using a protocol comprising ABA, PEG and a gelling agent in quantities that are specified in applicants' claims. The motivation to combine the two teachings is from Rutter et al. to produce large numbers of individual clones for reforestation purposes (column 1, lines 28-29). The Office contends that Levee et al disclose a protocol comprising placing cells on a support membrane which is subsequently transferred from one medium to another. Given the difficulty in handling plant cells, one skilled in the art would immediately recognize the advantage of the method of Levee et al to reduce the damage done to cells during manipulation of the cell cultures. The specific use of this reference is for the protocol utilizing support membranes and it is irrelevant what particular type of pine cells were

regenerated. The Office asserts that a 1.132 Declaration specifying the differences between transforming and regenerating hard and soft pines and addressing why the teachings of Wenck et al, Rutter et al and Levee et al should not be applied to the present application will be considered in determining patentability of the present application.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 31, 33-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-57 of application number 09/973,088. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 52-57 of application number 09/973,088 are drawn to a method of selecting transformed cells of the genus *Pinus* subgenus *Pinus* comprising culturing said transformed pine cells on a support membrane placed over a gel medium or placed over a layer which is over said medium wherein said medium comprises tissue culture constituents and wherein said layer is liquid and wherein said membrane is from polyester, polypropylene or

liquid permeable fluoropolymer fabric, and wherein a selection agent is contained within said gel medium or said layer.

Claims 1, 3, 31, 33-37 of the instant application are obvious over claims 52-57 of application '088 because the instant claims are drawn to a method of regenerating transformed pine plants from transformed cells of the genus *Pinus* subgenus *Pinus* (including Southern Yellow pine) comprising selecting transformed pine cells on a medium comprising a selection agent and wherein the selection agent is contained in a layer and said cells are cultured on a support membrane placed over said layer, or wherein said layer is a liquid layer, or wherein said support membrane is made from polyester, polypropylene or liquid permeable fluoropolymer fabric. It would have been obvious to one of skill in the art to modify the method from the '088 application by incorporating other members of the genus *Pinus* subgenus *Pinus* and other known differentiation and regeneration agents, given the recognition by those of ordinary skill in the art of the value of obtaining whole transformed pine plants for lumber.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.

Patent Examiner

Art Unit 1638

April 5, 2004